K 903360 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: GLENN N. BYRD DIVISION/BRANCH: DCD / STDDB

TRADE NAME: BAIR HUGGER model - 250 & - 500 COMMON NAME: THERMAL REGULATION SYSTEM

PRODUCT TO WHICH COMPARED: K873745 (BAIR HUGGER, MODEL 200)
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?		✓	- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?		✓	- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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ARRATIVE DEVICE DESCRIPTION

INTENDED USE: To Prevent Patient Hypothermia

DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the ices design, materials, physical properties and toxicology profile if ortant.

UMMARY: The Devices Submitted Are Identicle In Design, Performance, And Intended Use, As The Predicate Device. Temperature Output Levels To The Patient Are Also Identicle.

Packaging Is The Only Substantial Difference. The Devices Under Review Are Both Smaller In Size And Lighter In Weight Than The Predicate Device. This Is Due To The Elimination Of A Storage Compartment And Its Associated Steel Structural Components.

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: N/A

2. EXPLAIN WHY NOT SUBJECT TO 510(k): N/A

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: N/A

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: N/A

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: Model 250 - No Change Technologically. Model 500 - $\frac{1}{30}$ HP vs. $\frac{1}{20}$ HP motor, 115V vs. 125V, 9.5 amps vs. 7 amps, 850W Heating Element vs. 600W

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: Smaller HP motor saves weight, this resulted in increase of heating element wattage, however, maximum temp. output to patient is identicle to predicate device and all warnings trigger at same max. temp as predicate. Fuse for device is also identicle.

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: N/A

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: N/A

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: N/A

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: N/A

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: N/A

ATTACH ADDITIONAL SUPPORTING INFORMATION